

## **REMARKS**

The office action dated 2/27/04 indicates the following:

Claims 41-50, 51-64, 65-66 and 83-86 are withdrawn from consideration.

[Note: It is believed that the first indication in the office action that claims 77-78 are withdrawn from consideration is a typographical error. The Examiner is being asked to confirm this point.]

Claims 6, 11-14, 40 and 67-76 are objected to because of the use of the term "pad-like" structure. Note: these claims have been amended in formal respects to overcome this objection.

Claims 1-9, 11-20, 24-26, 28, 30, 33-40, 67-72, 75-76, 77-82 and 87-90 stand rejected under 35 USC 102 (b) on the basis of Engelman.

Claims 1-10 also stand rejected under 35 USC 102 (b) on the basis of Mercer.

Claims 27 and 29 stand rejected under 35 USC 103(a) as being unpatentable over Engelman.

Claim 32 stands rejected under 35 USC 103(a) as being unpatentable over Engelman in view of Swartz.

Claims 73-74 stand rejected under 35 USC 103(a) as being unpatentable over Engelman in view of Suzuki.

Claims 21-23 and 31 were indicated to be allowable if rewritten in independent form. **Pending the Examiner's review of this amendment these claims are being kept in their dependent form.**

Independent claims 1, 24, 35, 40, 67, 77 and 87 have been amended to define patentably over the cited references. It is submitted that Engelman and/or Mercer and/or the other cited references do not show teach or suggest the claimed invention, as discussed below.

Applicants' invention resides, in part, in the recognition that where there is a bony prominence in a body part (e.g., at the tip of the heel) there is a concentration of the overlying weight at that point and the concentrated weight is applied to a relatively small area at the interface between the bony prominence and the associated soft tissue layer. As shown and taught in the application, pressure (P) at a point is a function of the weight (W) at that point divided by the area over which the weight is distributed. When and where a body part rests directly on a support surface (e.g., a bed) and due to the presence and shape of the bony prominence, the **interface** area over which the weight is distributed is small, there is a resultant relatively **high and unhealthy** pressure at the **interface** between the bony prominence and the underlying soft tissue layer. The application of this pressure may cause the formation of ulcers in the body part, particularly, over time.

Applicants' invention also resides in the **protective means for enclosing the bony prominence and its associated body part such that the pressure at the interface between the bony prominence and its associated soft tissue layer is substantially reduced by increasing the effective area over which the weight is distributed.** The protective means functions to increase the effective area over which the concentrated weight at

**the interface between the bony prominence and its associated soft tissue** is distributed, thereby decreasing the pressure developed at the interface between the bony prominence and the underlying soft tissue layer and across the soft tissue layer. The shaping and contouring of Applicants' protective device and its application to a body portion containing a bony prominence in order to distribute the weight concentrated at the bony prominence over a greater area and volume is **not** shown, taught or suggested in the cited references.

By way of example, refer to Figs. 5, 6 and 8 of Engelman which show support for the leg and for immobilizing the leg. There is no showing or suggestion of providing support for the heel (or the heel bone) which is the body part containing a bony prominence and which is of particular concern to Applicants. Engelman shows how to support and raise the leg which tends to include a large bone and which covers a large area. Supporting the leg bone is not of specific concern to Applicants. Applicants are concerned with distributing the weight at the **interface between the bony prominence and its associated soft tissue layer** so as to decrease the pressure at that point. Engelman and Mercer are silent on this issue. Thus, Engelman does not address the problem addressed by Applicants and does not suggest Applicants' solution.

Mercer is directed to the formation of a lightweight cast useful for mending a broken bone. Mercer states at col. 4 lines 45 to 49, that padding material may be used to cushion and protect the leg and skin from the cast and to

prevent possible rubbing between them. There is no teaching or suggestion of distributing the weight concentrated at a bony prominence over a larger effective area and volume in order to reduce the pressure at the interface between the bony prominence and the underlying soft tissue layer.

In the Mercer and Engelman references, the body part is immobilized and/or not freely movable. In sharp contrast thereto, Applicants' prosthesis or protective device, when attached to a body part, allows the body part to be moved freely. In accordance with Applicants' invention, a user of the innovative protective device on his/her body part can generally freely move and orient the body part in any direction.

Thus, the Engelman and Mercer references do not anticipate the problem and solutions addressed and resolved by Applicants. Furthermore, combining Engelman and/or Mercer with the other references of record, Suzuki and Swartz et al, does not show, teach or suggest the claimed invention.

Claim 1 has been amended to incorporate the subject matter of claim 2 and to more specifically recite certain aspects of the invention. Claim 1, as amended, calls for: (a) a body part having a bony prominence tending to concentrate the weight of the body part over a small region; and (b) a protective device shaped to: (i) **enclose** the body part containing the bony prominence **including the bony prominence**; and (ii) **extend continuously between the body part containing the bony prominence and the support structure**. The protective device is shaped and located so as to increase the

effective area and volume over which the concentrated weight is distributed in the space between the bony prominence and the support surface.

Claim 1, as amended, is believed to define patentably over Engelman taken alone and/or in combination with the other references of record.

Claim 2 has been amended to emphasize that the surface area between the bony prominence and the underlying soft tissue over which the concentrated weight is distributed is increased from X to Y when Applicants' protective device is used. That is, the concentrated weight, W, at the bony prominence is distributed over an area Y when Applicants' protective device is used resulting in a pressure P2. The same weight, W, is distributed over an area X, which is smaller than Y, when the body part is in direct contact with a support surface, resulting in a larger pressure P1. This showing and teaching is not suggested in Engelman and/or in the other references. Accordingly Claim 2, as amended, is submitted to be patentable for its own reasons as well as those adduced for amended claim 1, from which it depends.

Claim 3 is submitted to be patentable for its own reasons as well as those adduced for amended claim 1, from which it depends.

Claims 11, 12 and 19 are submitted to be patentable for their own reasons as well as those adduced for claims 1 and 3 from which they depend.

Claim 4 has been amended to emphasize that a body part on which Applicants' protective device is mounted can be freely moved in any direction. There is no need to immobilize a body part to get the benefit of Applicants' protective device. As discussed above, this is not shown or taught in the cited

references. Accordingly, claim 4, as amended is submitted to be patentable for its own reasons as well as those adduced for amended claim 1, from which it depends.

Claims 5, 13-17, and 20 are submitted to be patentable for at least the same reasons as amended claims 1 and 4 from which they depend.

Claims 11, 12 and 19 are submitted to be patentable for at least the same reasons as claims 1 and 3 from which they depend.

Claim 6 is submitted to be patentable for its own reasons as well as those adduced for amended claim 1, from which it depends.

Claim 7 is submitted to be patentable for its own reasons as well as those adduced for amended claim 1, from which it depends.

Claims 8, 9, 10 and 18 dependent from claim 7, are submitted to be patentable for their own reasons as well as those adduced for amended claim 1 and claim 7 from which they depend.

**Claims 21-23, indicated to be allowable if rewritten in independent form, are being kept as originally presented pending the Examiner's review of this amendment.**

Independent claim 24 has been amended to emphasize that the protective device is applied to the body part and extends **continuously between the portion of the body part containing the bony portion and the support surface for increasing the effective area and volume over which the concentrated weight is distributed.** This is not shown, taught or suggested in Engelman taken alone or in combination with the other references of record.

Accordingly claim 24, as amended, is submitted to be patentable over the cited references.

Claim 25 is cancelled without prejudice.

Claims 26-30 and 32-34 are submitted to be patentable for their own reasons as well as those adduced for amended claim 24, from which they depend.

**Claim 31, indicated to be allowable if rewritten in independent form, has been amended to correct a typographical error and to depend from claim 24. Pending the Examiner's review of this amendment, claim 31 is being kept in a dependent form.**

Independent claim 35 has been amended, in a manner similar to that of claims 1 and 24, to emphasize that the protective structure is located between the bony portion of the body part and a support surface and to enclose the bony portion of the body part to be protected to increase the surface area of the interface over which the concentrated weight is distributed. Accordingly, claim 35 is submitted to be patentable over the cited references.

Claim 36, dependent from claim 35, has been amended to more specifically call for selected properties of the protective structure to have different values depending on the length of time the body part is to lie on the support surface. In so far as understood this is not shown taught or suggested in the cited references.

Claim 37 is cancelled without prejudice.

Claim 38, dependent from claim 35, has been amended to more specifically recite that selected properties of the protective structure change gradually as a function of time in order to gradually increase the area and volume over which the concentrated weight is distributed as a function of time. There is no suggestion of this in the references.

Claim 39, dependent from claim 35 has been amended to recite that selective characteristics of the protective structure undergo change as a function of time in order to reduce the pressure at the interface between the bony portion and its surrounding soft tissue layer, across the soft tissue layer, the interface between the soft tissue layer and the outer skin and between the outer skin and the protective structure. Again, this is not shown, taught or suggested in the cited references

Accordingly, claims 36, 38 and 39 are submitted to be patentable for their own reasons as well as those adduced for amended claim 35, from which they depend.

Claim 40 has been amended in a manner similar to claims 1 and 2 and is submitted to be patentable for the reasons discussed above.

Claim 67 has been amended in formal respects to overcome the Examiner's objection to "pad-like". The claim has also been amended to more clearly recite that the prosthesis includes a bone to soft tissue pressure reducing structure **implanted** at the site of the bony prominence to increase the contact area between the bony prominence and the surrounding soft tissue layer.

**Implanting a prosthesis** at the site of the bony prominence to increase the



contact area between the bony prominence and the surrounding soft tissue layer to increase the contact area over which the weight due to the body part and the bony prominence is distributed is not shown, taught or suggested in Engelman or in any of the other cited references. Accordingly it is submitted that claim 67, as amended, defines patentably over the cited references.

Claims 68-73, as amended, claim 74, and claims 75 and 76, as amended, dependent directly or indirectly from claim 67, are submitted to be patentable for their own reasons as well as those adduced for amended claim 67.

Claim 77 has been amended to recite that the protective device includes a hard shell structure of limited size to be applied to the area of the body part containing the bony prominence and wherein the size of the device is limited for enabling the body part to move freely. It is submitted that a limited size hard shell structure shaped to reduce the pressure developed at the interface between the bony prominence and its corresponding soft tissue layer is not shown, taught or suggested in the cited references. Accordingly it is submitted that claim 77, as amended, defines patentably over the cited references.

Claim 78 is cancelled without prejudice

Claims 79, as amended, 80, 81 and 82 dependent directly or indirectly from claim 77, are submitted to be patentable for their own reasons as well as claim 77.


Claim 87 has been amended to emphasize that the bone structure is of the type which has undergone amputation and where the amputated member requires a support surface and wherein there is pressure at the interface

between the amputated body part and the support surface for the body part. The claim, as amended, now calls for a pad-like structure to be placed between the amputated portion of the bone structure and the support surface for increasing the area over which the weight of the body part is distributed, thereby decreasing the pressure below the level that could cause an ulcer in the body part. This type of protection and the protective device is not shown or suggested in the cited references. Accordingly claim 87 is submitted to be patentable.

Claims 88, 89 and 90 dependent from claim 87 are submitted to be patentable for their own reasons, as well as those adduced for claim 87.

In summary, the allowance of the claims present in the application is respectfully requested.

Respectfully submitted

  
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